



GB04/03618



INVESTOR IN PEOPLE

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

REC'D 14 SEP 2004

WIPO

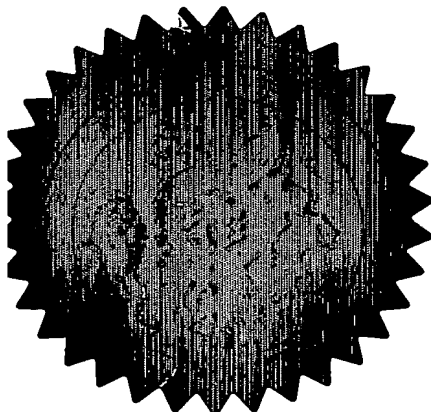
PC1

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.



Signed

Andrew Gersey

Dated 6 September 2004

**PRIORITY
DOCUMENT**

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

THE PATENT OFFICE

- 5 SEP 2003

NEWPORT

EWR/P205235GB

The Patent Office

Cardiff Road
Newport
South Wales
NP9 1RH

1. Your reference

2. Patent application number

(The Patent Office will fill in this part)

0320787.5

- 5 SEP 2003

3. Full name, address and postcode of the or of each applicant (underline all surnames)

Depuy International Ltd
St Anthony's Road
Leeds
LS11 8DT

6004733002

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

ENGLAND

4. Title of the invention

Flexible Image Guided Surgery Marker

5. Name of your agent (if you have one)

Urquhart-Dykes & Lord

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

Tower House
Merrion Way
Leeds
LS2 8PA

1644004

Patents ADP number (if you know it)

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)

Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

Yes

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
- See note (d))

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	0
Description	11
Claim(s)	2 DL
Abstract	0
Drawing(s)	3 1 2

10. If you are also filing any of the following, state how many against each item.

Priority documents	0
Translations of priority documents	0
Statement of inventorship and right to grant of a patent (Patents Form 7/77)	0
Request for preliminary examination and search (Patents Form 9/77)	1 ✓
Request for substantive examination (Patents Form 10/77)	0
Any other documents (please specify)	0

11. I/We request the grant of a patent on the basis of this application.

Signature

Date



4/9/03

12. Name and daytime telephone number of person to contact in the United Kingdom

Edward Rolfe
0113 245 2388

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

DUPLICATE

-1-

FLEXIBLE IMAGE GUIDED SURGERY MARKER

The present invention relates to a flexible bone marker for use during image guided surgery.

Image Guided Surgery (IGS) procedures are well known. For example, during
5 orthopaedics such procedures are used to enable a predetermined site on a patient's bone to be located, even after movement of the bone. The precise calculation of the location of the bone site allows the confident navigation of surgical apparatus which will operate at the site.

It is important during orthopaedic IGS that a bone marker, used as a reference for
10 calculating locations on a patient's bone, does not move relative to the bone to which it is anchored. Typically, bone markers move due to the softness of the bone in which the bone marker is anchored. The softness of the bone makes it difficult to achieve a solid, rigid fixation. Additionally, the surgeon may knock the bone marker once it has been anchored, causing the marker to move or pull slightly at the anchor point in the bone. This will cause
15 inaccuracy in the calculation of the specified bone site as the marker will have moved relative to the bone. Further the fixation grip of the bone marker at the anchor point may be reduced if the force applied to the bone marker was sufficient to damage the bone at the anchor point. In such cases, the surgeon must re-register the bone marker causing significant delay and frustration.

20 The present invention provides a flexible bone marker for use in IGS which tolerates forces applied to the bone marker and also reduces the force applied to the marker/bone anchor point.

According to a first aspect of the present invention, there is provided a bone marker for use in image guided surgery, comprising a support having an anchor mechanism for anchoring
25 the support in a bone, the bone marker further comprising at least one reference member detectable by an image guided system, the at least one reference member being attached to

the support, in which the support comprises at least one limb which is resiliently deformable.

The bone marker of the present invention has the advantage that the risk of the bone marker moving inadvertently relative to the bone during IGS is significantly reduced. Due to the flexibility of the support of the bone marker, a force applied to the marker is absorbed by the support of the marker rather than the at the marker's anchor point. This significantly reduces the force applied to the anchor point thereby reducing the chance of moving the bone marker within the anchor point. This also reduces the chance of damaging the anchor point which may cause the marker to become loose. The resiliency of the support ensures that it quickly returns approximately exactly back to its original position in order for the procedure to continue as normal.

Further, as the anchor site is required to bear much smaller loads, the force required to fix the marker into the bone can be reduced. This can minimise damage to the bone at the anchorage point as it is possible to use much smaller fixation devices to securely anchor the marker.

The bone marker has an anchor for anchoring the bone marker into a bone, and a support to which at least one reference member is attached. The anchor part can be permanently fixed to the support. Preferably, the anchor is releasably attachable to the support.

Preferably, the anchor comprises a fixation member for anchoring the bone marker within the bone, and a coupling member for releasably attaching the support to the fixation member. The fixation member can be permanently fixed to the coupling member. Preferably, the fixation member is releasably attached to the coupling member.

Preferably, the fixation member has a substantially constant cross-sectional shape along its length. Preferably the cross-section of the fixation member is generally round. For example, the cross-section may be circular. Preferably the width of fixation member at its widest point is not smaller than 5 mm, preferably not smaller than 3mm, more preferably not smaller than 2 mm, and especially not smaller than 1 mm. Preferably the width of

fixation member at its widest point is not greater than 10 mm, preferably not greater than 5 mm, more preferably not greater than 2 mm, and especially not greater than 1mm.

Preferably, the fixation member is narrower at a first end which is to be inserted into the bone, and wider at a second end which is to protrude from the surface of the bone and to be attached to the coupling member. Preferably the fixation member has a generally smooth shank capable of being hammered into the bone. Preferably the fixation member has a threaded shank and is capable of being screwed into the bone. Preferably the fixation member comprises a first narrow cylindrical shank, a second wide cylindrical shank, and a frustoconical shank tapering outwardly from the first narrow shank to the second wide shank. The fixation member can be made from materials which are suitable for insertion into a bone. Particularly preferred materials can include certain stainless steels. Preferably the anchor comprises two fixation members. Preferably, the anchor comprises more than two fixation members. However, any appropriate mechanism for anchoring a bone marker in a bone may be used.

Preferably, the coupling member is an adjustable coupling member. Preferably, the coupling member has a first attachment means for removably attaching the coupling member to a fixation member. Preferably, the coupling member has a second attachment means for removably attaching the coupling member to the support. Preferably, the coupling member enables the support to be rotated about the fixation member. Preferably the coupling member comprises at least one pivot point to enable the support to be rotated about the longitudinal axis of the fixation member. Preferably, the coupling member comprises at least one pivot point to enable the support to be rotated between a position which is parallel to the longitudinal axis of the fixation member, and a position which is perpendicular to the longitudinal axis of the fixation member. Preferably, a pivot point comprises a bearing which can be locked into position so that the support can be rotated about the pivot point and locked into a desired position. However, any appropriate coupling member for attaching a support to a fixation member may be used.

The support can comprise only one limb. Preferably, the first end of the limb is attached to the anchor.

Preferably the support comprises a plurality of limbs. The limbs can be identical in dimensions and configuration. However, preferably the limbs are not identical. All of the limbs can be attached to the anchor. However, preferably the support comprises at least one leg limb having a first end which is attached to the anchor and a second end to which at least one arm limb is attached. Preferably, a first end of an arm limb will be attached to the leg limb. The leg limbs can be identical in dimensions and configuration. However, preferably the leg limbs are not identical. The arm limbs can be identical in dimensions and configuration. However, preferably the arms limbs are not identical.

Preferably, the ratio of the axial length of a limb to its diameter is no less than 2:1, more preferably no less than 4:1, and especially no less than 8:1.

A reference member can be attached to a limb at any point on the limb. Further, more than one reference member may be attached to a limb. However, preferably a single reference member is attached to a limb at the end of a limb.

Preferably, at least one of the limbs of the support is resiliently deformable. Preferably, a resiliently deformable limb is sufficiently resilient so that the limb returns back to approximately its original position after it has been deformed. Preferably, a resiliently deformable limb is sufficiently resilient so that once deformed within its elastic limit, it returns to a position back not more than 0.25 mm from its original position, more preferably not than 0.2 mm from its original position and especially not more than 0.1 mm from its original position.

Preferably, the tip of a resiliently deformable limb can be deflected up to 45 degrees away from its axis, before its elastic limit is exceeded. More preferably, the tip of a resiliently deformable limb can be deflected up to 90 degrees away from its axis, before its elastic limit is exceeded.

Preferably, the tip of a resiliently deformable limb can be deflected perpendicularly away from its axis by up to a distance of 70% of the axial length of the limb, before its elastic limit is exceeded. More preferably, the tip of a resiliently deformable limb can be

deflected perpendicularly away from its axis by up to a distance of 100% of the axial length of the limb, before its elastic limit is exceeded.

Preferably, a resiliently deformable limb will return back to its original shape within a reasonable period of time. Preferably, a reasonable time period is no more than 3 seconds.

5 More preferably, a reasonable time period is no more than 2 seconds. Especially preferably, a reasonable time period is no more than 1 second. However, the period of time in which the limb should return back to its original position will depend on the requirements of the IGS system used. Many materials exhibit the characteristics of being sufficiently resilient so that it returns back to its original position within a reasonable
10 period of time. Examples of such materials are dampened elastomers and shape memory alloys.

Preferably, a resiliently deformable limb is sufficiently stiff so that it does not deform significantly under its own weight or its own weight plus the weight of a mass attached to it (e.g. a limb may have at least one reference member or at least one other limb attached to
15 it). Preferably, a resiliently deformable limb is sufficiently stiff so that when it is held horizontally it deforms by no more than 0.25 mm, more preferably no more than 0.2 mm and especially preferably no more than 0.1 mm.

Preferably, a resiliently deformable limb is hollow along its longitudinal axis. Preferably, the ratio of the outer diameter of the resiliently deformable limb to its inner diameter is no
20 more than 5:4, more preferably no more than 3:2, especially preferably no more than 1:1, and even more preferably no more than 3:1.

A resiliently deformable limb can be made of any material having the aforesaid properties. Preferably, a limb is made from a damped elastomer material having the aforesaid properties. More preferably, a limb is made from a shape memory alloy having the
25 aforesaid properties. Especially preferably, a limb is made from a tightly wound helical spring having the aforesaid properties, especially in which each turn of wire abuts the previous turn of wire, when not deformed. Preferably the abutting surfaces of the wire are flat. More preferably, all the surfaces of the wire are flat. Preferably, the cross-sectional

shape of the wire is rectangular. More preferably, the cross-sectional shape of the wire is square. Preferably, the ratio of the depth of the wire to the width of the wire is no more than 3:1, more preferably no more than 2:1, and especially preferably no more than 1:1. Preferably, the ratio of the width of the wire to the depth of the wire is no more than 2:1,
5 more preferably no more than 3:1 and more preferably no more than 4:1.

Preferably, the wire of the tightly wound helical spring will be made of stainless steel. However, the wire of the tightly wound helical spring may be any material for fulfilling the aforesaid requirements of a resiliently deformable limb.

Where the support comprises a plurality of limbs, one of the limbs of the support member
10 may be rigid. Further, more than one of the limbs of the support member can be rigid. Preferably, a rigid limb is sufficiently stiff so that it does not deform significantly upon the application of an external force. Preferably, a rigid limb is made from stainless steel. However, any material suitable for use during surgical procedures, which when formed into a limb having the aforesaid requirements, can be used.

15 The number and arrangement of limbs and reference members of a bone marker will depend on requirements of the IGS system used. The support of the present invention can have at least one reference member, or two reference members attached to it, or more. Preferably, there will be three reference members. Preferably, the reference members are arranged to be co-planar. Preferably, the reference members are arranged to be define two
20 planes of reference, perpendicular to each other. Preferably, the reference members are arranged to define three planes of reference. Suitable arrangements of reference members for use in IGS systems, such as star arrangements, are well known to a person of ordinary skill in the art and therefore a detailed discussion of such systems is not included within this description so as not to obscure the present invention.

25 Preferably the reference members are detectable by an IGS system. Preferably, the reference members can be detected by the IGS system wirelessly.

Preferably, the reference members are active members. Preferably, the active members transmit a signal to the IGS system. Preferably the active members broadcast the signal to be detected by the IGS system. Preferably, the signal is an ultrasonic signal. Preferably, the signal is an infrared signal. Preferably, the signal is a radiowave signal. Preferably, the active members continuously transmit a signal. Preferably, the active members transmit a signal at regular intervals. Preferably, the size of an active member is generally 40x40x5mm.

Preferably, the reference members are passive members. Preferably, the reference members reflect a signal transmitted by the IGS system, and the IGS system detects the reflected signal. Preferably, the signal is an ultrasonic signal. Preferably, the signal is an infrared signal. Preferably, the signal is a radiowave signal. Preferably, the reference members are spherical members. Preferably, the reference members are made of any material suitable for reflecting the any of the aforementioned signals. Preferably, the size of a passive member is generally 100x100x5mm. More preferably, the size of a passive member is generally 10x10x5mm.

Suitable reference members, their materials, and methods for detecting and calculating their location, for use in IGS systems are well known to a person of ordinary skill in the art and therefore a detailed discussion of such systems is not within this description so as not to obscure the present invention.

Preferably, the height of the bone marker is no smaller than 15cm, more preferably no smaller than 10cm, especially no smaller than 5 cm. Preferably, the height of the bone marker is no greater than 20cm, more preferably no greater than 15cm, especially no greater than 10cm.

Preferably, the width of the bone marker at its widest point is no smaller than 1cm, more preferably no smaller than 5 cm, and especially no smaller than 10cm. Preferably the width of the bone marker at its widest point is no greater than 15cm, more preferably no greater than 10cm, and especially no greater than 5cm.

An embodiment of the invention will now be described, by way of example only, and with reference to the accompanying drawings, in which:

Figure 1 shows a front view of a bone marker according to one embodiment of the present invention.

5 Figure 2 shows a front view of a bone marker according to a first embodiment of the present invention, illustrating the flexibility of the bone marker.

Figure 3 shows front view of a bone marker according to a second embodiment of the present invention.

Referring now to the drawings, figure 1 shows a bone marker designated generally by
10 reference 1 for use in an IGS system (not shown). Bone marker 1 comprises an anchor 2 and a support 3 removably attached to each other.

Anchor 2 comprises a fixation member 4 for anchoring the bone marker in a bone (not shown) and an adjustable mechanical coupling 5. The adjustable mechanical coupling is removably attached to the fixation member 4.

15 Fixation member 4 has a first cylindrical shaft 7 having a first end comprising a number of sharp projections 6, for securing onto the bone and a second end, distal to the first end. Fixation member 4 has a second cylindrical shaft 9 having a greater diameter than the diameter than the first shaft 7. A frustoconical portion 8 tapered outwardly from the second end of first shaft 7 to a first end of second shaft 9, connects the first shaft 7 to the
20 second shaft 9.

Adjustable mechanical coupling 5 comprises a first screw 10 for attaching the adjustable mechanical coupling 5 to the fixation member 4. The first screw 10 has a threaded shank (not shown) receivable by a socket in the second cylindrical shaft 9, and a head 11 for fastening the screw 10 into shaft 9. An adjustable arm 12, extending perpendicular to the
25 longitudinal axis of the fixation member 4, is attached to head 11 at a first end, so as to be

rotatable about the head 11. The adjustable arm 12 can be locked into position by tightening screw 13. A shaft 15, extending parallel to the longitudinal axis of the fixation member 4 is attached to a second end of adjustable arm 12 so as to be rotatable about the second end of the adjustable arm. A nut 14, which is rotatable independently of the shaft 15, is provided for locking the shaft 15 into position. The shaft 15 has a head 16 fixed to end of the shaft 15 distal to the end attached to the adjustable arm 12. Head 16 has a first end for receiving a screw 17. Screw 17 has a mechanism for releasably securing the support 3. Screw 17 can be loosened and tightened by rotation of screw head 18 located at a first end of screw 17. Screw 17 has a plurality of teeth located at a second end, distal to the first end, of screw 17, which interlock with a plurality of teeth located on the first end of head 16. Therefore, when screw head 18 is loosened, screw 17 can be rotated about an axis parallel to the length of the screw, and locked into position by tightening screw head 18.

Support 3 of the bone marker 1 comprises leg limb 20 and a body part 21. Leg 20 and body part 21 are permanently attached to each other.

Leg 20 is resiliently deformable. Leg 20 comprises a tightly wound helical spring member 22, having a number of successive abutting turns of wire made of a material such as stainless steel. The spring member 22 allows for extremely flexible movement away from its axis when an external force is applied, but returns very quickly to its original position once the force has been removed. The spring member 22 has a first end which is removably fixable in the adjustable mechanical coupling 5, by insertion into releasable screw 17. Spring member 22 has a second end, distal to the first end, permanently attached to body 21.

Body part 21 comprises two rigid short arm limbs 23 and one rigid long arm limb 24 arranged in a 'T' formation. Leg 20 is attached to the body 21 at the intersection of the arms limbs 23, 24. The arms 23, 24 are made from a single component of stainless steel.

Reference members 25 are permanently attached to the end of each of the short and long arm limbs 23, 24. Reference members 25 are detectable by an IGS system for use in calculation of the location of the bone marker.

Once the bone marker 1 has been anchored into the bone, the IGS system will be calibrated so that the location of the reference members 25 relative to a predetermined site on a patient's bone can be registered. Once the relative position between the reference members 25 and the bone site has been registered, it is possible to determine the location of the bone site by knowing the location of the reference members only, even after movement of the bone. This allows, for example surgical apparatus to be accurately navigated to the bone site, to operate on the bone site, even if the bone has been moved.

As illustrated in figure 2, which shows the bone marker 1 of figure 1, leg 20 will deform if the bone marker 1 is knocked during use in surgery. Therefore, leg 20 will absorb some of the force applied to the bone marker 1, thereby reducing the force applied at the anchor point in the bone.

Figure 3 illustrates a second bone marker designated generally by reference 10, according to a second embodiment of the present invention. Equivalent parts of this bone marker 10 and the bone marker 1 of figures 1 and 2 have equivalent reference numerals.

Bone marker 10 comprises an anchor 2 and a support 3. Support 3 comprises a leg limb 20 and a body part 21. Unlike the bone marker of figure 2, leg 20 is a non-flexible member 27, made of a rigid material such as stainless steel. Further, the short arms limbs 23 and long arm limb 24 each comprise a separate tightly wound helical spring member designated by references 28, 29 and 30. Each of the spring members 28, 29 and 30 allow for extremely flexible movement away from their axes when an external force is applied to them, but return very quickly to their original position once the force has been removed.

As illustrated in figure 3, the short arm limbs 23 and long arm limbs 24 will deform if they are knocked during use in surgery. Therefore, the arms 23 and 24 will absorb some of the

-11-

force applied to the bone marker 1, thereby reducing the force applied at the anchor point in the bone.

CLAIMS:

1. A bone marker for use in image guided surgery, comprising a support having an anchor mechanism for anchoring the support in a bone, the bone marker further comprising at least one reference member detectable by an image guided system,
5 the at least one reference member being attached to the support, in which the support comprises at least one limb which is resiliently deformable.
2. A bone marker as claimed in claim 1, in which the support further comprises at least one limb which is rigid.
3. A bone marker as claimed in claim 1, in which a resiliently deformable limb
10 comprises a tightly wound helical spring.
4. A bone marker as claimed in claim 3, in which the abutting surfaces of the wire are flat.
5. A bone marker as claimed in claim 1, in which a resiliently deformable limb is made from a damped elastomer.
- 15 6. A bone marker as claimed in claim 1, in which a resiliently deformable limb is made from a shape memory alloy.
7. A bone marker as claimed in claim 1, in which the ratio of the outer diameter of a resiliently deformable limb to its inner diameter is at most 3:1.
8. A bone marker as claimed in claim 1, in which the anchor mechanism comprises at
20 least one fixation member for anchoring the bone marker in the bone, and a coupling member for coupling the support to the fixation member.
9. A bone marker as claimed in claim 8, in which the coupling member is adjustable to allow rotation of the support about the fixation member.

10. A bone marker as claimed in claim 8, in which the at least one fixation member is a threaded screw.
11. A bone marker as claimed in claim 10, in which the threaded screw is 2mm or less in diameter.
- 5 12. A bone marker as claimed in claim 1, in which the reference members transmit signals.
13. A bone marker as claimed in claim 1, in which the reference members reflect signals.
14. An image guided surgery system which comprises:
 - 10 a. a bone marker as claimed in any of the preceding claims,
 - b. a processing system for calculating the position of the reference members and a location on the bone relative to the position of the reference members,
 - 15 c. an actuation system for moving an apparatus to a location calculated by the processing system.

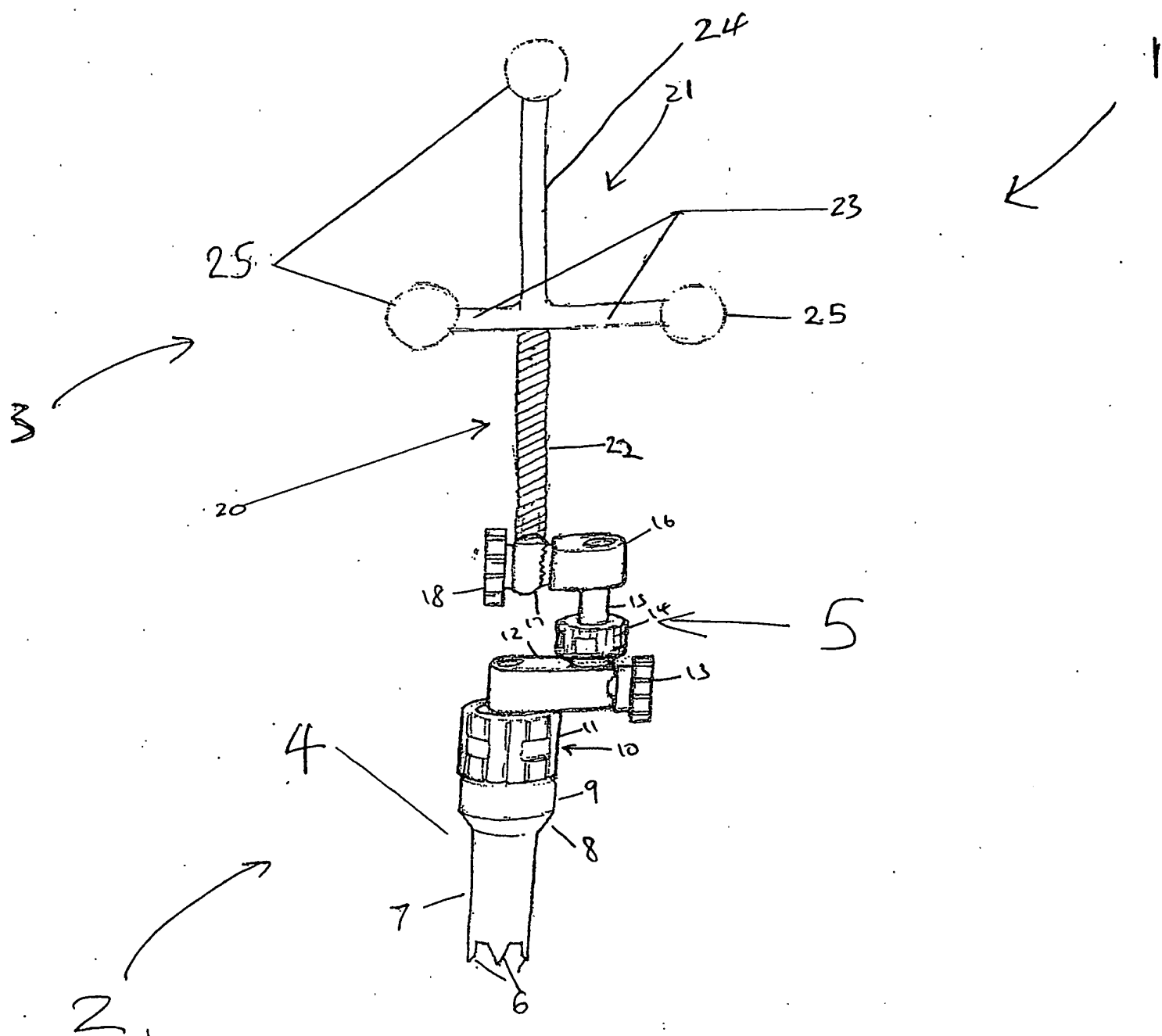


Figure 1

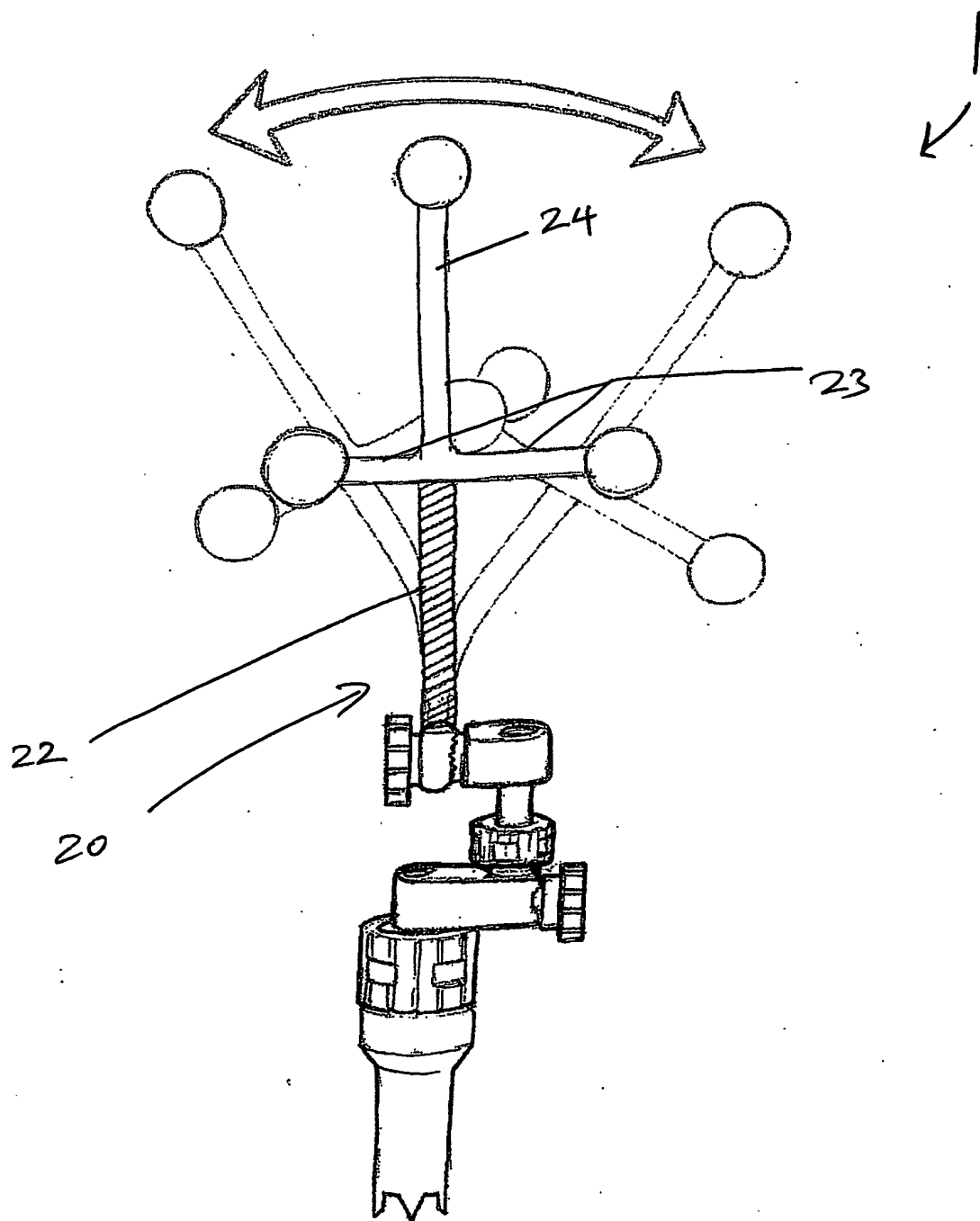


Figure 2

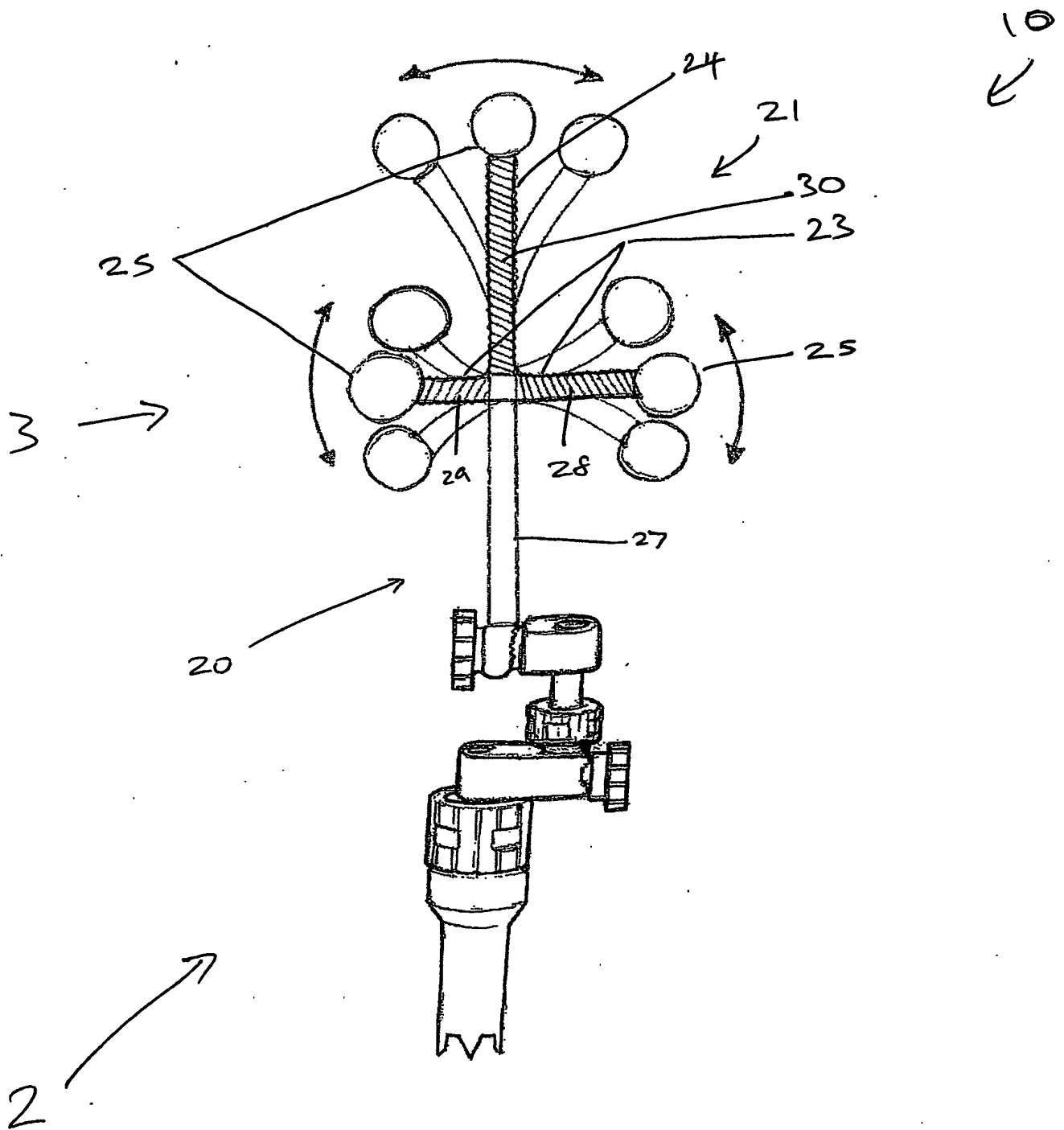


Figure 3

PCT/GB2004/003618

